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PATENT DIVISIONAL DIRECTION

PATENT IN-DEPTH EXAMINATION DIVISIONAL SUBDIRECTION

BIOTECHNOLOGY, PHARMACEUTICAL AND CHEMICAL AREA

PHARMACEUTICAL AREA IN-DEPTH EXAMINATION DEPARTMENT

COORDINATION

PCT Patent Docket PA/a/2006/009833

Request 1                    Issue: In-depth examination result report.

Mexico City, April 28, 2009

JAVIER UHTHOFF ORIVE

Agent of

ACTELION PHARMACEUTICALS LTD.

ORIGINAL

RECEIVED

Hamburg No. 260

Name:

Juárez

Date:

06600, Mexico City

Signature:

REF.: Your PCT Patent Application No. PA/a/2006/009833 filed on February 23, 2005.

As a result of the in-depth examination, performed under the provisions of Articles 53 of the Industrial Property Law (LPI) and 42 of the Regulations of the Industrial Property Law (RLPI), you are hereby informed of the following:

The in-depth examination was performed based on the following application documents:

Specification: Pages 1 to 4 and 6 to 56, as originally filed; page 5 as filed in your voluntary amendment letter No. 62638 of October 4, 2006.

Claims: No. 1 to 14, as originally filed.

1.- The following objections regarding the clarity of the claims, are raised under the provisions of Articles 47 section III of the Industrial Property Law and 29 of the Industrial Property Law Guidelines.

The claims have clarity problems because:

- a) On claim 9 the phrase "...characterized in that it is used as a medicament" by the phrase: "...to be used as a medicament."

Therefore, the Applicant must submit:

A new claim set in which the claims are clear and concise and cannot exceed the content of the specification. They shall be drafted in terms of the technical features of the invention, in order to comply with the provisions of Articles 47, section III of the Industrial Property Law and 29 of the Regulations of the Industrial Property Law.

2.- During the in-depth examination process performed to your patent application we found the Search Report of Application No. PCT/EP2005/001879 corresponding to the claimed priority, publication No. WO 2005/118548 A1 of 15.12.2005 performed by the European Patent Office, wherein the following document is cited:

- WO 01/68609 A1 (D1)

3.- In order to comply with the provisions of Article 17 of the Industrial Property Law which states that for determining that an invention is new and the result of an inventive step, the state of the art on the filing date of the patent application or being the case, of the acknowledged priority, shall be considered. You are hereby informed that upon determining the state of the art according to Articles 12 section II and the above cited one, we found that document D1 affects the novelty and inventive step of the present application, according to the following:

i) D1 (formulas I and II) generally discloses the compounds derived from 1,2,3,4-tetrahydroisoquinoline which are the same as those disclosed in your application and which are used as orexin receptor antagonists, however, as the compounds of the present application are a selection of the compounds generally disclosed in D1, in this case, it is obvious for a person skilled in the art to obtain the compounds disclosed in your application from the teachings of D1, as there have been no comparative tests which demonstrate an improvement or an unexpected result of the present application compounds regarding the state of the art, and that with this being thus evident the presence of an inventive step.

According to the cited state of the art, it is concluded that the subject matter claimed in your claim set lacks novelty and inventive step, not complying with the provisions of Articles 16 and 12 sections I and III of the Industrial Property Law. From the foregoing, the Applicant is requested according to Article 45 of the Regulations of the Industrial Property Law, to submit the necessary clarifications regarding the novelty and inventive step of his application.

The clarifications or modifications made either in the specification, the drawings and/or the claims, must not have additional matter with further scope than the matter originally filed in the application and/or elements which support additional claims, such that what is established in Article 55 BIS of the Industrial

**Property Law is fulfilled.**

Also, you will have to pay the current fee and show the corresponding receipt.

In order to satisfy these requirements, you are hereby granted a two month term as of the next day of the present notification letter, being informed that if this requirement is not fulfilled on the stated term your patent application will be considered abandoned under the provisions of Arts. 55 and 58 of the Industrial Property Law.

The present Office Action corresponds to the first in-depth examination request, which is issued, further from what has been furnished above, pursuant to Article 13 of the Agreement setting Rules and Criteria for resolution of several procedures before the Mexican Patent Office, published in the Federation Official Gazette on August 9, 2004.

The undersigned signs the present letter under Articles 6 fractions III and XI and 7 bis 2 of the Industrial Property Law (Federation Official Gazette (D.O.F.) 27/06/1991, amended on 02/08/1994, 26/12/1997, 17/05/1999, 26/01/2004, 16/06/2005 and 25/01/2006); Articles 1, 3 section V letter a) subletter ii), 4, and 12 fractions I, II, III, IV and VI of the Mexican Industrial Property Institute Guidelines (D.O.F. December 14 1999, amended on 01/07/2002, 15/07/2004, 28/07/2004 and 7/09/2007); Articles 1, 3, 5 section V letter a) subletter ii), 16 fractions I, II, III, IV and VI and 30 of the Organic Statute of the Mexican Industrial Property Institute (D.O.F. December 27 1999, amended on 10/10/2002, 29/07/2004, 04/09/2004 and 13/09/2007); 1, 2 and 5 letters e) and i), and and penultimate paragraph of the Agreement by which faculties are delegated to the Deputy General Directors, Coordinator, Divisional Directors, Regional Offices Directors, Divisional Deputy Directors, Department Coordinators and other Subordinates of the Mexican Institute of Industrial Property (D.O.F. December 15 1999, amended on 04/02/2000, 29/07/2004, 04/08/2004 and 13/09/2007).

SINCERELY

THE DEPARTMENT COORDINATOR